NOT FOR PUBLICATION

UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

BAUSCH HEALTH IRELAND LIMITED, et al., Plaintiffs, v. PADAGIS ISRAEL PHARMACEUTICALS LTD et al., Defendants.	**Civil Action No. 20-5426 (SRC) (CONSOLIDATED)** **OPINION & ORDER**

CHESLER, U.S.D.J.

This matter comes before the Court on the motions *in limine* filed both by Plaintiffs Bausch Health Ireland Limited, Bausch Health Americas Inc., and Bausch Health US, LLC (collectively, "Bausch") and by Defendants Padagis Israel Pharmaceuticals LTD and Padagis US LLC (collectively, "Padagis.") Plaintiffs have filed four motions *in limine* and Defendants have filed two. For the reasons that follow, Plaintiffs' first and third motions will be granted, Plaintiffs' second motion will be denied, Plaintiffs' fourth motion will be granted in part and denied in part, and Defendants' motions will be denied.

This case concern patents related to the pharmaceutical products Duobrii® and Bryhali®. Padagis is a pharmaceutical company which has filed ANDA Nos. 214285 and 214626 to produce generic versions of those pharmaceutical products. Bausch owns U.S. Patent Nos. 10,251,895 ("the '895 patent"), 10,426,787 ("the '787 patent," and together with the '895 patent, the "Combination Patents"), 8,809,307 ("the '307 patent") and 10,478,502 ("the '502 patent").

The specification of the Combination Patents refers to a clinical study ("the 201 Study") of a formulation identified as IDP-118, which has the same formulation as Bausch's Duobrii® product. The Final Pretrial Order contains this stipulation of fact:

> 26. On January 22, 2014, Bausch registered the 201 Study, a Phase II clinical trial involving IDP-118, to ClinicalTrials.Gov as Study No. NCT02045277.

I. Plaintiffs' first motion *in limine*

Plaintiffs' first *in limine* motion seeks to preclude Defendants from arguing at trial that statistical significance is required to satisfy the synergy limitations of the '895 and '787 patents. Plaintiffs argue, in short, that this Court construed the synergy limitations during claim construction, that Defendants could have asserted statistical significance claim limitations at that point but did not assert constructions which did so, and that arguments at trial which view the synergy limitations as requiring statistical significance are inconsistent with this Court's Markman constructions. Padagis summarizes its arguments in opposition as follows:

> the evidence Bausch seeks to exclude does not relate to the construction or the meaning of the claim terms in the Patents-in-Suit. Instead, it relates to the highly factual issue of whether Bausch can present sufficient evidence to demonstrate that Padagis's accused product actually practices the claims as construed. Thus, there is no conflict or inconsistency between Padagis's evidence and any of the claim constructions in this case.
> . . .
> In both its infringement and written description analyses, this Court must determine whether the data disclosed in the Combination Patents shows that IDP-118 is actually capable of providing synergistic efficacy and a synergistic reduction in an adverse event. To make that determination, the Court must account for the natural variability in the data and the likelihood that a calculation of synergy reflects a true effect of IDP-118 and not just random chance or variance observed in the clinical study. . . Assessing whether a calculation of synergy reflects an actual effect of IDP-118 is the purpose of Padagis's evidence on statistical analysis and statistical significance.
> . . .
> Claim construction is only the first step of the patent infringement analysis, however, and the second step, a factual inquiry, requires comparing the allegedly

> infringing product with the construed claims. Padagis's evidence of statistical analysis and statistical significance is relevant to this second step. Statistical significance does not speak to how a POSA would understand or define synergy, and therefore, it was not an issue during claim construction. Instead, statistical significance addresses a different question: **does a limited sample of observed data establish that a drug actually produces the level of efficacy (or adverse events) that is required to meet the definition of synergy?**

(Defs.' Opp. Br. at 1, 6-7, 8; emphasis added.)

The question in boldface reflects the essence of Defendants' understanding of what they believe to be a fundamental issue in the infringement inquiry.[1] The problem for Defendants is that it relies on the proposition that a data analysis showing statistical significance is required to "establish that a drug **actually** produces [an effect.]" This Court first inquires: where did Defendants get this "actually" requirement? It seems that the effect of the "actually" requirement is to revise the construction of the claim language: agreeing with the "actually" requirement would have the effect of inserting new claim limitations.[2]

The relevant claims state: "the composition . . . is capable of providing synergistic efficacy and synergistic reduction . . ." (Claim 1 of the '787 patent; claim 1 of the '895 patent.) The language of the relevant claims requires that the compositions be "capable of providing" the synergistic effects. The plain language does not expressly require that the composition "actually produces" the synergistic effects, nor did this Court construe the language to have that meaning. Defendants use the words, "establish" and "actually produces," to suggest a new requirement that "actually produces" must be "establish[ed]" by a data analysis which demonstrates statistical

[1] Similarly, Defendants formulate the central question as whether there is "sufficient evidence showing that the drug ***actually meets***" the synergy limitations. (Defs.' Opp. Br. at 14.)
[2] One might also view the "actually" requirement as an attempt to heighten the standard of proof applied to the infringement analysis, demanding more than a preponderance of the evidence.

significance.[3] As to the synergy limitations, the patentee bears the burden of proof, by a preponderance of the evidence, that the accused infringer will likely market a product that is "capable of providing" the synergistic effects, as this Court has construed them. See Glaxo Inc. v. Novopharm Ltd., 110 F.3d 1562, 1570 (Fed. Cir. 1997) ("The relevant inquiry is whether the patentee has proven by a preponderance of the evidence that the alleged infringer will likely market an infringing product.")

To support their position, Defendants appear to rely considerably on the opinions of their expert, Dr. Betensky. For example: "Dr. Betensky uses her analysis of statistical significance to . . . measure the reliability of any conclusions that can be drawn from the data in the Combination Patents." (Defs. Opp. Br. at 15.) Defendants have not persuaded this Court that their expert's opinions about how she might measure the reliability of conclusions about the data in the patent are even relevant to the infringement inquiry this Court must conduct, much less that Dr. Betensky should determine the structure for this Court's infringement inquiry.

Defendants further argue that their proposed "actually produces" test "goes to the sufficiency and weight of evidence when comparing the construed claims to Padagis's accused product in the second step of the infringement analysis." (Defs.' Opp. Br. at 8.) Again,

[3] Similarly, Padagis contends that this Court must conduct "the factual analysis of whether a set of data can reliably support a conclusion that a particular product provides synergy." (Defs.' Opp. Br. at 10.) What is Defendants' basis for this proposed "reliably support a conclusion" test? Defendants have not persuaded that either Federal Circuit law or the language of the claims at issue require such a test. As to the source in the patents, Defendants point only to "the disclosure of p-values in Table 6 of the Combination Patents . . . reinforces that those in the art, including the inventors, recognized that statistical analysis is necessary to draw reliable conclusions from clinical trial data, not because it demonstrates how the inventors did or did not define synergy." (Defs.' Opp. Br. at 10-11.) The matter of how skilled artisans ensure that their conclusions from clinical trial data are reliable is not at issue in the infringement inquiry in this case.

Defendants have failed to persuade that statistical significance is required by the construed claims or relevant to the Court's application of the preponderance of the evidence standard to the evidence of infringement. Nor have Defendants persuaded this Court that their "actually produces" test has a foundation in either the patents or patent law; this Court rejects Defendants' argument that evidence of statistical significance is relevant to the legal sufficiency of Plaintiffs' evidence of infringement. As Plaintiffs contend, Defendants' attempt to add in a statistical significance requirement is inconsistent with the Court's claim constructions and an improper attempt to revise them or, alternatively, an attempt to change the burden of proof of infringement.

Plaintiffs' first motion *in limine* will be granted. Defendants are precluded from arguing at trial that statistical significance is required to satisfy the synergy limitations of the '895 and '787 patents.

II. Plaintiffs' second motion *in limine*

Plaintiffs' second *in limine* motion seeks to exclude ClinicalTrials.Gov postings from evidence at trial and to preclude Defendants from arguing that the postings are invalidating prior art. Plaintiffs make three arguments: 1) the "Wayback Machine" evidence was not timely disclosed; 2) Defendants cannot prove that the proffered postings were publicly available at the relevant times; and 3) the postings reflect an experimental use that falls within an exception to the definition of prior art. Plaintiffs' brief refers to the postings evidence in Exhibit DX-519 as well as Exhibits DX-063 through DX-066. Plaintiffs describe one document (Bruno Dec. Ex. 23) as "exemplary;" that document bears the same Bates numbers as Exhibit DX-064.

Plaintiffs use the phrase, the "Wayback Machine" evidence, to refer only to the document

in Exhibit DX-519 that Padagis contends was found in an internet archive (named the "Wayback Machine"), which is alleged to contain ClinicalTrials.Gov posting evidence regarding a date or dates in the past. The parties do not dispute that Padagis did not produce any Wayback Machine documents until July of 2022. Bausch argues that the Wayback Machine documents should be excluded pursuant to Federal Rule of Civil Procedure 37(c)(1), which states:

> (1) Failure to Disclose or Supplement. If a party fails to provide information or identify a witness as required by Rule 26(a) or (e), the party is not allowed to use that information or witness to supply evidence on a motion, at a hearing, or at a trial, unless the failure was substantially justified or is harmless.

Padagis, in opposition, contends: 1) that it properly and timely disclosed its theory that the ClinicalTrials.Gov postings are invalidating prior art in the Invalidity Contentions served on March 5, 2021; and 2) that Dr. Binu Alexander, Bausch's 30(b)(6) witness designated to testify on Bausch's behalf on the topic of Bausch's submission of information to ClinicalTrials.Gov, "testified that version 1 of the ClinicalTrials.Gov Study record is reflected in DX-064," one of the exhibits that Bausch moves to exclude.[4] (Defs.' Opp. Br. at 4).

As to Exhibit DX-519, Defendants respond that the reason for the late disclosure is that DX-519 is itself a response to Plaintiffs' late disclosure of their "date printed" theory. This Court need not resolve this dispute over DX-519, the Wayback Machine, and late disclosure, for two reasons: 1) exhibit DX-064, together with Dr. Alexander's testimony about that exhibit, sufficiently serve Defendants as evidence of the posting on which they rely; and 2) Bausch has made no demonstration that it has been harmed by the late disclosure of the Wayback Machine evidence: its single sentence of explanation of prejudice is vague and conclusory. (Pls.' Br. at

[4] Plaintiffs' brief, however, does not characterize Exhibit DX-064 as Wayback Machine evidence, but cites a different exhibit, DX-519.

12.)

Defendants, in opposition, focus on Exhibit DX-064. Defendants contend, in short, that the factual foundation for their proffer of DX-064, and all essential facts about the ClinicalTrials.Gov posting on which Defendants rely, have been admitted by Dr. Alexander, "Bausch's 30(b)(6) witness designated to testify on Bausch's behalf on the topic of Bausch's submission of information to ClinicalTrials.Gov." (Defs.' Opp. Br. at 10.) In support of the argument that Dr. Alexander testified that "version 1 of the ClinicalTrials.Gov Study record is reflected in DX-064," Padagis cites to his deposition transcript. (Alexander Dep. at 53-56, Cheek Dec. Ex. 3.) In the cited deposition testimony, Defendants' counsel began by identifying the document shown to Dr. Alexander by a range of Bates numbers. (Id. at 53:2-9.) These Bates numbers match the Bates numbers on Exhibit DX-064, as shown in Cheek Dec. Ex. 2. Exhibit DX-064 states a submitted date for version 1 of January 22, 2014. (Cheek Dec. Ex. 2 at HALOBET0019359.) Dr. Alexander testified in confirmation of the basic facts about the contents of the document before him, including that it disclosed the active ingredients in IDP-118 and their concentrations, and stated that the document reflected version 1 of the ClinicalTrials.Gov posting as posted "around January 24, 2014." (Alexander Dep. at 53-59.)

Bausch argues as if it was blindsided by the Wayback Machine evidence, but it is clear that Padagis properly and timely disclosed its invalidity theory based on the ClinicalTrials.Gov postings. Bausch also argues as if Defendants' ClinicalTrials.Gov invalidity case depends entirely on Exhibit DX-519, but it does not. Defendants' invalidity case relies substantially on the deposition testimony of the 30(b)(6) witness, Dr. Alexander. Plaintiffs have been given sufficient notice of the substance of Defendants' ClinicalTrials.Gov invalidity case. This Court

finds no basis to conclude that the late disclosure of the Wayback Machine evidence was harmful to Plaintiffs, given all the other evidence and information about the postings theory that was timely disclosed.

Plaintiffs' other arguments attempt to show that Defendants cannot prove their ClinicalTrials.Gov invalidity case, on two grounds: 1) Defendant cannot prove that the proffered listings were publicly available at the relevant time; and 2) the postings reflect an experimental use that falls within an exception to the definition of prior art. Both arguments seek summary judgment on Defendants' ClinicalTrials.Gov invalidity case. They are arguments that Plaintiffs may properly make at trial, but do not provide a proper basis to grant a motion to exclude. This Court finds no basis to preclude Defendants from presenting their ClinicalTrials.Gov invalidity case at trial.

Plaintiffs' second *in limine* motion will be denied.

III. Plaintiffs' third motion *in limine*

Plaintiffs' third *in limine* motion seeks to preclude Defendants from offering expert testimony at trial on the subject of an untitled letter (the "Letter"), dated March 31, 2022, from the FDA to Bausch. (Bruno Dec. Ex. 22.) Plaintiffs contend that expert testimony about the Letter should be excluded, pursuant to Federal Rule of Evidence 403, as irrelevant, confusing, and a waste of time. Plaintiffs contend, in brief, that the Letter addressed questions of whether certain Duobrii® marketing materials violated advertising standards in the Federal Food, Drug & Cosmetic Act ("FDCA"), and that the Letter has no relevance to the infringement inquiry in this case. Plaintiffs argue that FDCA standards and the standards of patent law are different and distinct.

In opposition, Padagis responds that "the FDA Warning letter is probative of disputed infringement issues because that letter explains the FDA's conclusion that the same clinical trial Bausch relies on to prove infringement of the Synergy Limitations was inadequate to support conclusions of synergy." (Defs.' Opp. Br. at 1.) Defendants point to the part of the Letter which states:

> The webpage creates a misleading impression regarding the efficacy and mechanism of action of Duobrii because it draws conclusions based on data that are inadequate to support such conclusions. The claims of "demonstrated synergy" and "superior efficacy" versus the aggregated results of two monotherapies on the webpage are based on data derived from post hoc analyses of a single phase 2 trial, of limited sample size, which compared Duobrii separately to its individual components and vehicle. We acknowledge the statement, "Post hoc analysis of a phase 2 clinical trial" is included on the webpage. However, this does not mitigate the misleading impression created by these claims and presentations because the phase 2 trial was not designed to support conclusions comparing the efficacy of Duobrii to its aggregated components, minus the vehicle effect. Because this analysis was conducted post hoc, there was no prespecified statistical procedure controlling for type 1 error rate (false positive rate) in this phase 2 trial, so it is not possible to ascertain whether the findings were attributable to treatment with Duobrii and its components, or merely due to chance. As a result, these findings are exploratory (hypothesis-generating). Therefore, claims and presentations that draw conclusions (e.g., "demonstrated synergy" and/or "superior efficacy") are misleading.

(Letter at 5.)

This Court agrees with Bausch that the Letter is not relevant to the issues of patent infringement in this case, and that Defendants' arguments to the contrary confuse the issues. There are multiple problems with viewing the letter as probative of issues in this case. To start with, the Letter does not address the clinical study data disclosed in the Combination Patents but, instead, two articles published in the Journal of Drugs in Dermatology. (See Letter at 5.) Padagis argues: "Both of those articles relate to the 201 Study that is disclosed in the

Combination Patents." (Defs.' Opp. Br. at 3.) The Court finds that expert testimony about a letter which addresses neither the disclosures of the patents at issue, nor anything about Defendants' proposed generic products, has no relevance to the issues of patent infringement in this case and does indeed confuse the issues of infringement.

Defendants argue that expert testimony about the Letter is relevant to their defense to infringement, because it speaks to the question of whether: "this data is sufficient to support a conclusion that IDP-118 or Padagis's ANDA product is capable of providing synergistic efficacy or a synergistic reduction in an adverse event." (Defs.' Opp. Br. at 3.) Defendants fail to persuade this Court that the Letter's reasoning to support the assertion that certain promotional statements are misleading under the FDCA is probative of the infringement question in this case, which is whether Defendants are likely to market a product which infringes the "capable of providing synergistic" effects limitations in the claims at issue. Rather, as Bausch contends, expert testimony about the Letter is likely to confuse the issues.

Defendants contend as well that expert testimony about the "Letter is also relevant to Bausch's claims of commercial success as a relevant secondary consideration of nonobviousness." (Defs.' Opp. Br. at 7.) Again, this Court does not perceive the relevance of the Letter, and whether certain promotional materials are misleading under the FDCA, to questions of commercial success as a secondary indication of nonobviousness of the claims at issue.

Plaintiffs' third *in limine* motion will be granted.

IV. Plaintiffs' fourth motion *in limine*

Plaintiffs' fourth *in limine* motion seeks to preclude Defendants from presenting at trial

three theories which Plaintiffs contend are new and not disclosed in Defendants' contentions of noninfringement or invalidity:

> (1) Padagis's generic product does not infringe based on differences or potential differences between Bausch's branded product Duobrii® (also known as IDP-118), and Padagis's generic product; (2) the Asserted Claims would have been obvious on grounds that the IDP-118 lotion formulation would have been obvious to a person of ordinary skill in the art and that the synergy limitations of the asserted claims are inherent properties of the IDP-118 lotion formulation; and (3) Padagis's generic product does not infringe because Bausch's branded product IDP-118, which Padagis presumes to be the same as Padagis's generic product, does not demonstrate *statistically significant* synergistic efficacy and/or *statistically significant* reduction of at least an adverse event as these limitations have been construed by the Court.

(Pls.' Br. at 1-2.)

As to the first alleged new theory, concerning noninfringement based on differences, Padagis responds that Plaintiffs bear the burden of proof of infringement at trial, and that, at trial, Defendants will simply respond to the testimony given by Bausch's experts. Padagis contends that what Bausch contends is a new theory is merely Defendants' response to the testimony of Bausch's expert, Dr. Stein Gold, regarding "her mistaken belief that Duobrii was identical to Padagis's combination product." (Defs.' Opp. Br. at 4.) Defendants argue that, to the extent Bausch argues at trial that Duobrii® is identical to their ANDA product, they should be allowed to respond. The Court finds Defendants' position entirely reasonable. The first theory is not a new undisclosed theory of noninfringement, but a response contesting a factual assertion or assumption by one of Bausch's experts. Padagis may respond to testimony asserting or assuming that the two products are identical.

As to the second alleged new theory, concerning obviousness based on inherent properties of IDP-118, Bausch acknowledges that Padagis timely presented this Invalidity

Contention: "The recited claims of synergy are inherent properties of the recited topical formulation." (Pls.' Br. at 10.) Bausch contends that Defendants' expert Dr. Stern presented a new theory in his reply expert report, where he stated:

> [T]o the extent that IDP-118 provides synergistic efficacy and/or a synergistic reduction in adverse events, those results are simply the inherent and natural result of an obvious drug formulation applied to patients suffering from psoriasis.

(Pls.' Br. at 12.) Bausch argues that this is a new invalidity theory because the original contention referenced the obviousness of a genus ("the recited topical formulation"), while this statement from Dr. Stern references the obviousness of one included species (IDP-118).

Bausch focuses on a sentence from the Stern reply report that appears in this context:

> **2. <u>The Synergy Limitations Are Directed To Inherent Properties Of The Composition</u>**
>
> 32. I understand from counsel that in the context of obviousness, a limitation is inherent, and therefore not entitled to patentable weight, when the limitation is the natural result of the combination of prior art elements. As I explained in my Opening Report, the prior art disclosed each of the Formulation Limitations of IDP-118 and therefore, the formulation of IDP-118 is simply an obvious combination of prior art elements. See Stern Op. Rep. at ¶¶135-373. As I also explained in my Opening Report, the efficacy and adverse events observed with IDP-118, including any synergistic efficacy or reduction in adverse events, are the natural result of the reaction of the patient's body to IDP-118. Accordingly, to the extent that IDP-118 provides synergistic efficacy and/or a synergistic reduction in adverse events, those results are simply the inherent and natural result of an obvious drug formulation applied to patients suffering from psoriasis.

(Stern Reply Report ⁋ 32, Bruno Dec. Ex. 27.) The sentence Bausch points to does not propose a new theory of invalidity. Instead, paragraph 32 in the Stern reply report presents a concrete example of the general theory disclosed in the Invalidity Contentions, which is reflected in the subheading in underlined boldface that precedes it. The concrete example is drawn from the specification disclosure of IDP-118 and the associated 201 Study. It is commonplace for a

general theory to be illustrated and discussed through the presentation of concrete examples, and it is certainly sensible when a particular embodiment is the preferred embodiment[5] and has a starring role in the patent specifications, as IDP-118 has in the Combination Patents. There is nothing new in paragraph 32 of the Stern reply report; Bausch cannot have been surprised that an expert discussed the principal example in the specification to support a theory of invalidity that had been stated more broadly in the Invalidity Contentions.

In opposition, Padagis cites the Federal Circuit's statements in Cuozzo:

> It is a "long-established rule that 'claims which are broad enough to read on obvious subject matter are unpatentable even though they also read on nonobvious subject matter.'" Thus if the mechanical embodiment is obvious, claim 10 is obvious.

In re Cuozzo Speed Techs., LLC, 793 F.3d 1268, 1281 (Fed. Cir. 2015) (citations omitted). The situation here is analogous. In Defendants' Invalidity Contentions, the contention that "[t]he recited claims of synergy are inherent properties of the recited topical formulation" appears in the context of their theory that claim 1 of the '895 patent is obvious, which appears in the context of their theory that all asserted claims of the '895 patent are obvious. (Bruno Dec. Ex. 14 at 89-99.) Just as in Cuozzo, Padagis contends claim 1 is obvious because IDP-118 is an embodiment of claim 1 and is an obvious formulation. Cuozzo makes clear that such an approach to proving obviousness is "long-established." 793 F.3d at 1281. Padagis also quotes a district court decision which states:

> Par has not pointed to any authority requiring TWi to show that the claimed food effect limitations are inherent in every formulation claimed by the '576 patent. In the obviousness context, examples are enough.

[5] In the specification of both Combination Patents, the composition identified as the preferred embodiment in Table 3 has the same formulation as the composition identified as IDP-118 in Table 4.

Par Pharm., Inc. v. TWi Pharm., Inc., 120 F. Supp. 3d 468, 475 (D. Md. 2015). Dr. Stern's statements in his reply report seek to demonstrate the obviousness of claim 1 by showing that an example is obvious. Federal Circuit law does not require Padagis to show that all formulations contained in the genus claim of claim 1 are obvious; one example is enough.

As to the second alleged new theory, the Court finds no basis to exclude the proffered testimony.

The third alleged new theory deals with the matter of whether the synergy limitations require statistically significant effects, already discussed in connection with Plaintiffs' first *in limine* motion. For the reasons already stated, presentation of this theory is barred.

Plaintiffs' fourth *in limine* motion will be granted in part and denied in part. As to the third alleged new theory, regarding statistical significance requirements, the motion will be granted. As to the first and second alleged new theories, concerning noninfringement based on differences, and Dr. Stern's reply report, the motion will be denied.

V. Defendants' motions *in limine*

Defendants filed two *in limine* motions. The first *in limine* motion, in brief, seeks to preclude Plaintiffs' experts from opining on the substance of the law in the matter of the untitled FDA Letter, already discussed in regard to Plaintiffs' third *in limine* motion. Because this Court has decided that the Letter is inadmissible as not relevant, and has decided to grant Plaintiffs' motion to exclude expert testimony about the letter, this moots Defendants' first *in limine* motion.

Defendants' second *in limine* motion seeks to preclude Plaintiffs from using an experimental use defense for failure to disclose it in their invalidity contentions. Padagis

contends that Bausch's Invalidity Contentions do not disclose an experimental use defense in regard to the ClinicalTrials.Gov postings. Bausch, in opposition, contends that it did so, but points to no clear statement in the Invalidity Contentions asserting an experimental use defense. Instead, Bausch points to its general contention that the ClinicalTrials.Gov postings are not prior art against the Combination Patents, as well as a few scattered words concerning experiments and investigations in its response to Defendants' Invalidity Contentions: 1) a ClinicalTrials.Gov posting identifies IDP-118 as the "experimental treatment" in the context of its assertion that the postings do not constitute prior art and do not disclose the composition of IDP-118 (Bruno Dec. Ex. 31 at 34, 35); 2) the posting discloses "the investigation of a composition containing . . ." (id. at 3-5); and 3) the posting discloses a formulation "as being under investigation" (id. at 124.) These citations do not establish adequate disclosure of an experimental use defense. Instead, they disclose a contention not in dispute, that a clinical study was done that was an investigation of an experimental treatment. These references did not put Defendants on notice of an experimental use defense to the contention that ClinicalTrials.Gov postings constituted invalidating prior art. The use of the defense was not properly disclosed.

Defendants ask this Court to preclude Plaintiffs from arguing an experimental use defense at trial, so as to enforce the Local Patent Rules requiring timely disclosure of invalidity contentions, and cite two sister court cases in support of their contention that courts in this district enforce the Local Patent Rules without requiring a showing of prejudice. In the alternative, Defendants argue that they have suffered prejudice, as they have been deprived of the opportunity to explore the experimental use defense in fact discovery. Plaintiffs, in opposition, contend that Defendants engaged in considerable fact discovery about the ClinicalTrials.Gov

postings and the 201 Study of IDP-118. Plaintiffs point out that Defendants have not identified any particular fact or facts on which they would have sought additional discovery: "For instance, Padagis has not identified a single factor among the 13 in the experimental use analysis that necessitated additional documents or deposition testimony." (Pls.' Opp. Br. at 8.) Plaintiffs argue that they should not be precluded from presenting the experimental use defense based on an unsupported and vague allegation of prejudice.

In this case, this Court is disinclined to bar use of the defense solely on the basis of "enforcement" of the Local Patent Rules, in the absence of any persuasive showing by Padagis that it has suffered prejudice from the late disclosure. Instead, because it appears that Defendants have engaged in considerable discovery about the postings and the underlying study, and have suffered no actual harm from the delay in disclosure, Bausch will be allowed to present the experimental use defense at trial. Defendants' second *in limine* motion will be denied.

For these reasons,

IT IS on this 21st day of September, 2022

ORDERED that Plaintiffs' first motion *in limine* (Docket Entry No. 173) is **GRANTED**; and it is further

ORDERED that Plaintiffs' second motion *in limine* (Docket Entry No. 175) is **DENIED**; and it is further

ORDERED that Plaintiffs' third motion *in limine* (Docket Entry No. 177) is **GRANTED**; and it is further

ORDERED that Plaintiffs' fourth motion *in limine* (Docket Entry No. 179) is **GRANTED** in part and **DENIED** in part; and it is further

ORDERED that, as to the third alleged new theory, regarding statistical significance requirements, Plaintiffs' fourth motion *in limine* is **GRANTED**; and it is further

ORDERED that, as to the first and second alleged new theories, concerning noninfringement based on differences, and Dr. Stern's reply report, Plaintiffs' fourth motion *in limine* is **DENIED**; and it is further

ORDERED that Defendants' first motion *in limine* (Docket Entry No. 169) is **DENIED** as moot; and it is further

ORDERED that Defendants' second motion *in limine* (Docket Entry No. 171) is **DENIED.**

s/ Stanley R. Chesler
Stanley R. Chesler, U.S.D.J